



NDA 21-574/S-010

Andrx Pharmaceuticals, LLC
Attention: Ms. Janet Vaughn
Sr. Director, Regulatory Affairs
2945 West Corporate Lakes Blvd.
Weston, FL 33331

Dear Ms. Vaughn:

Please refer to your supplemental new drug application dated January 18, 2008, received January 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fortamet (metformin HCl extended-release) Tablets.

We acknowledge receipt of your submission dated July 17, 2008.

This supplemental application is in response to our supplement request letter dated November 19, 2007, and proposes labeling revisions to the **DESCRIPTION, INDICATIONS AND USAGE**, and **PRECAUTIONS** sections of the package insert.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert) submitted July 17, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-574."

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Mary Parks
7/29/2008 09:14:08 AM